Implementation manual
for
barcoding using GS1 global standards for tracing and tracking of pharmaceuticals and drugs for exports

To facilitate compliance with DGFT Public Notice No. 59(RE-2010)/2009-2014 dated the 30th June, 2011, this implementation manual is being made available for adoption by manufacturers/exporters of pharmaceuticals and drugs.

Section A: Primary level Packaging: (With effect from 1st July, 2012)

Requirement at Primary Level Packaging**:-**

Incorporation of 2D (GS1 DataMatrix) barcodes on medicines at primary level packaging encoding unique product identification code (GTIN) and Unique Serial Number following GS1 global standards.

Barcode Symbology**:** GS1 DataMatrix

Note:

- In case the importing country has mandated a specific requirement, the exporter can adhere to the same and it would not be necessary to comply with the above requirement.
- Where product is packed in a mono carton (e.g. ointments, eye/ear drops etc), barcode encoding GTIN and unique serial number should be marked on the mono carton itself.
- The above barcoding requirements shall be **in addition** to existing statutory labeling & marking requirements.

Primary Level Packaging: Is defined as the first level of packaging in direct contact with the product and marked with an AIDC (Automatic Identification and Data Capture) data carrier either on the packaging or on a label affixed to the packaging. It may consist of a single item or group of items for a single therapy such as a Kit.

GTIN (Global Trade Item Number): It is the GS1 identification key used to uniquely identify each product type/variant. It is created using a GS1 or U.P.C. Company Prefix number. GTIN can be of 14 digits (i.e. GTIN -14) or 13 digits (i.e. GTIN -13) or 12 digits (i.e. GTIN -12) or 8 digits (i.e. GTIN – 8).

As per above the requirement on primary packaging, barcode symbology to be used is GS1 DataMatrix. For the same GTIN-14 data structure of GTIN is required to be encoded in the barcode.

GTIN-14 data structure can be derived from GTIN-13 or GTIN-12 (UPC) or GTIN–8 by prefixing the required number of zeros to convert into a total of 14 digits as per the matrix below.

Figure 1

Data Structures	**GTIN -14 Format**													
GTIN-13	0	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}
GTIN-12	0	0	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}
GTIN-8	0	0	0	0	0	0	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8

Generation of GTIN-13:

GTIN-13: GTIN-13 is the 13-digit GS1 Identification Key used to identify each product type/variant and is composed of the GS1 Company Prefix, Item Reference, and a Check Digit.

Data structure of GTIN-13 :

GS1 Company Prefix						>	<	**Item Reference**				**Check Digit**
N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}

GS1 Company Prefix Number: A number allocated by GS1 India or any other GS1 member organization to the applicant company using which they can generate GS1 keys for unique identification of its products, locations, services etc.

Item Reference: A component of the Global Trade Item Number (GTIN) assigned by the manufacturer/brand owner to create a unique GTIN for each product variant/ type.

Check Digit : The last digit of a GTIN, calculated based on the preceding digits. This digit is used to check that the code being generated has been correctly composed. Check digit is calculated using the check digit calculator available at GS1 India's website: http://www.gs1india.org

Steps to generate a GTIN-13 number:-

1) Use company prefix number allocated by GS1 to the applicant company
2) Assign item reference number of applicant company's choice to each product type/variant
3) Calculate check digit using Check Digit Calculator
   (available at http://www.gs1india.org)

Note: GS1 company prefix number "8901107" is used as an example throughout this document. The manufacturer/brand owner has to use the company prefix number issued by GS1 India or any other GS1 member organizations in other countries.

Example:

GS1 Company Prefix						>	<	**Item Reference**				**Check Digit**
8	9	0	1	1	0	7		0	0	0	0	1	1

The above example:

- Uses company prefix number "8901107"
- Has been assigned item reference number " 00001" by applicant company
- "1" is the check digit calculated based on preceding 12 digits using check digit calculator

Generation of GTIN – 14 format from GTIN – 13 :

Data Structure	**GTIN -14 Format**													
GTIN-13	0	8	9	0	1	1	0	7	0	0	0	0	1	1

The above example:

- Uses "0" as the first digit to generate GTIN-14 data format from a GTIN - 13.
- Uses company prefix number "8901107"

- " 00001" has been assigned as item reference number by applicant company
- "1" is the check digit calculated based on preceding 13 digits using check digit calculator

Similarly GTIN-14 data format can also be derived from GTIN-12 & GTIN -8 by prefixing the required number of zeros to convert into a total of 14 digits as explained in the above matrix (Figure 1)

Representation of GS1 DataMatrix barcode encoding GTIN & unique serial number :

a) In the example below, representation of GTIN & Serial Number in GS1 DataMatrix symbology , is shown on primary packaging level.



(01)08901107000011
(21)abcd12345

It is mandatory to print data encoded in barcodes as human readable information, as shown above.

The parentheses (brackets) are not encoded in the bar code and they are represented in human readable form only for highlighting the application identifier number with in the brackets.

In the above example

(01)	Is the Application Identifier to indicate that the data following it is the GTIN
08901107000011	Is the GTIN
(21)	Is the Application Identifier to indicate that the data following it is the serial number of the product which should be alpha-numeric and of variable length field varying from 1 to 20 digits
abcd12345	Is the serial no. of primary package

b) For primary packaging of small pharmaceuticals where due to space constraints, barcoding may not be possible, GTIN and unique serial number shall be printed in human readable form following GS1 standards.

In the example below, representation of GTIN & unique serial Number in human readable form is shown on primary level packaging

GTIN : 08901107000011
Serial : abcd12345

Manufacturers can provide GTIN-13 or GTIN-12 or GTIN-8 instead of GTIN-14 data format alongwith Serial Number in human readable form on primary level packaging.

Section B: Secondary Level Packaging (With effect from 1st January, 2012)

Requirements at Secondary Level Packaging :- Incorporation of barcodes (GS1 – 128 i.e 1D or GS1 DataMatrix i.e 2D) encoding unique product identification code (GTIN), Expiry Date, Batch Number and Serial Number of the Secondary package.

Barcode Symbology: GS1-128 or GS1 DataMatrix or GS1 Databar

Secondary Level Packaging**:** Is defined as a level of packaging that may contain one or more primary packages or a group of primary packages containing a single item.

NOTE: There may be additional intermediate packaging levels above the secondary level packaging, but below the Shipper/Carton Tertiary level packaging. These intermediate packaging levels are not required to be barcoded at this time. Examples of these exclusions include:

- Inner packs (bundles)
- Intermediate packs (inner case)

As per above the requirement on secondary packaging, barcode symbology to be used is GS1-128 or GS1 DataMatrix. For the same GTIN-14 data structure of GTIN is required to be encoded in the barcode .

At Secondary level packaging, the barcode should encode the following information:

1) GTIN using application identifier (01)
2) Expiry Date in YYMMDD format using application identifier (17)
3) Batch/Lot Number using application identifier (10)
4) Serial No. of the secondary package using application identifier (21)

Note:

- GTIN of secondary level packaging should be different from GTIN of primary and shipper package.
- The above barcoding requirements shall be **in addition** to existing statutory labeling & marking requirements.
- The parentheses (brackets) are not encoded in the bar code and they are represented in human readable form only for highlighting the application identifier number with in the brackets.
- Fixed length data fields will always precede variable length fields.
- It is mandatory to print data encoded in barcodes as human readable information.
- In case the importing country has mandated a specific requirement, the exporter can adhere to the same and it would not be necessary to comply with the above requirement.
- For detailed specs refer to GS1 General Specifications available at : http://www.gs1india.org.in/gs1barcodes/pc_index.htm

Steps for Generation of Product identification Code (GTIN) at Secondary Level Packaging:

Refer to steps for generation of GTIN-14 format in Section-A (Figure 1) above.

Example of GS1 DataMatrix symbology (2D):

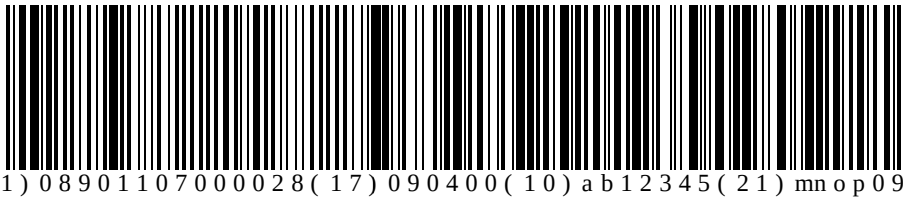
Using GS1 DataMatrix symbology, encoding of GTIN, Expiry Date, Batch number and serial number is represented schematically as below:-



(01)08901107000028
(17)090400(10)ab12345
(21)mnop09876

Example of GS1-128 barcode symbology (1D):

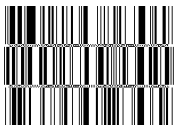
Using GS1 128 barcode symbology, encoding of GTIN, Expiry Date, Batch number and serial number is represented schematically as below:-



Not more than 48 characters can be encoded in a single GS1 – 128 barcode. If the total number of characters exceeds 48, it should be split in two barcodes on a single label.

Example of GS1 Databar symbology (1D):

Using GS1 Databar symbology, encoding of GTIN, Expiry Date, Batch number and serial number is represented schematically as below:-



(01)08901107000028(17)090400
(10)ab12345(21)mnop09876

In the above examples

(01)	Is the Application Identifier to indicate that the data following it is the GTIN
08901107000028	Is the GTIN
(17)	Is the Application Identifier to indicate that the data following it is the expiration date of the product in YYMMDD format
090400	Is the expiration date of the product in YYMMDD format (April 09 in this case)
(10)	Is the Application Identifier to indicate that the data following it is batch or lot number of product.
ab12345	Is the batch / lot number of the product
(21)	Is the Application Identifier to indicate that the data following it is the serial number of the product which should be alpha-numeric and of variable length field varying from 1 to 20 digits
mnop09876	Is the serial no. of secondary package

Section C: Tertiary Level Packaging (With effect from 1st October, 2011)

Requirements at Shipper/Carton/Tertiary level packaging:- Incorporation of GS1-128 barcode symbology (1D) encoding GTIN of the Shipper/Carton/Tertiary level packaging package, expiry date, batch number of the product and serial number (SSCC) of the Shipper/Carton/Tertiary level packaging .

Barcode Symbology: GS1-128.

As per above the requirement on Shipper/Carton/Tertiary level packaging, barcode symbology to be used is GS1-128. For the same GTIN-14 data structure of GTIN is required to be encoded in the barcode.

Shipper/Carton/Tertiary level packaging: Is defined as a level of packaging that shall contain one or more primary/secondary levels of packaging and can be considered as logistics unit (homogeneous/heterogeneous packages).

SSCC (Serial Shipping Container Code) : Is used for the unique identification of each Shipper/Carton/Tertiary level package as a logistic unit. It is composed of an extension digit, GS1 Company Prefix number, serial number of the Shipper/Carton/Tertiary level packaging and a check digit.

The tertiary level packaging can either be homogenous or heterogeneous as explained below:

Homogenous package: Is defined as a package containing multiple units of the same (only one) product packaging type. If a Shipper/Carton/Tertiary level packaging is a homogeneous package then there shall be two barcodes on the label containing GTIN, Expiry Date, Batch no encoded in the first barcode and SSCC encoded in the second barcode as represented schematically in figure – 2.

Heterogeneous package: Is defined as a package containing multiple units of different (more than one) product packaging type. If a Shipper/Carton/Tertiary level packaging is a heterogeneous package then there shall be only one barcode on the label encoding SSCC as represented schematically in figure – 3.

Data structure of Serial Shipping Container Code (SSCC):

Extension Digit	GS1 Company prefix > < Serial reference number																Check Digit
N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}	N_{14}	N_{15}	N_{16}	N_{17}	N_{18}

Steps to generate, SSCC (18 digits shipper identification code)**:-**

1) The Extension digit is used to increase the capacity of the Serial Reference within the SSCC. It is assigned by the company that constructs the SSCC. The Extension digit ranges from 0-9.
2) Use company prefix number issued by GS1 India or any other GS1 member organizations in other countries
3) Internally generated unique serial reference number to identify each Shipper/Carton/Tertiary level package..
4) Calculate check digit using Check Digit Calculator (available at http://www.gs1india.org)

Extension Digit	GS1 Company prefix > < Serial reference number																Check Digit
1	8	9	0	1	1	0	7	0	0	0	0	0	0	0	0	1	8

The above example:

- Uses “1” as the first digit as extension digit to generate SSCC
- Uses company prefix number “8901107”
- Has been assigned serial reference number “ 000000001”
- Is the check digit calculated based on preceding 17 digits using check digit calculator

Homogeneous Packaging:

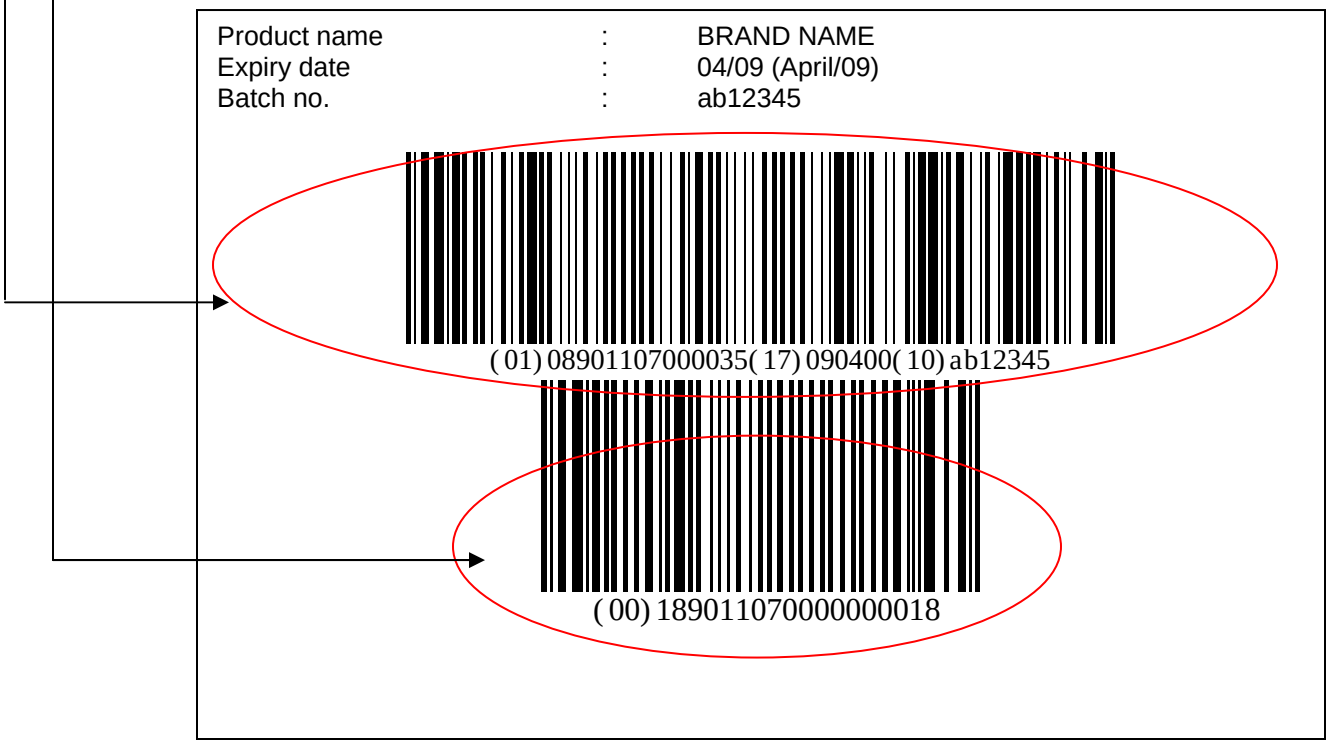
R*equirements for the homogeneous package: Homogenous* Shipper/Carton/Tertiary level packaging shall have two barcodes as represented schematically in figure – 2:

The first barcode contains:

1) Product Identification code (GTIN) using application identifier (01)
2) Expiry Date in YYMMDD format using application identifier (17)
3) Batch/Lot Number using application identifier (10)

The second barcode:

a. SSCC (Serial Shipping Container Code) to identify individual Shipper/Carton/Tertiary level packaging uniquely using application identifier (00)



(Figure -2)

Note: GTIN of shipper level packaging should be different from GTIN of primary and secondary package. *Refer to steps for generation of GTIN-14 format in Section-A (Figure 1) above.*

In the above example:-

The first barcode represents:

(01)	Is the Application Identifier to indicate that the data following it is the GTIN-14 data format
08901107000035	Is the GTIN of Shipper/Carton/Tertiary level packaging.
(17)	Is the Application Identifier to indicate that the data following it is the expiration date of the product in YYMMDD format
090400	Is the expiration date of the product in YYMMDD format (April 09 in this case)
(10)	Is the Application Identifier to indicate that the data following it is batch or lot number of the product.
ab12345	Is the batch / lot number of the product.

The second barcode represents:

(00)	Is the Application Identifier to indicate that the data following it is the numeric serial number of the Shipper/Carton/Tertiary level packaging.
189011070000000018	Is the 18 digit numeric serial no. of the Shipper/Carton/Tertiary level packaging.

Heterogeneous packaging:

The requirements for the tertiary/shipper package/logistics unit (heterogeneous package):

Heterogeneous packaging shall have only one barcode encoding SSCC as represented schematically in figure – 3

SSCC (Serial Shipping Container Code) to identify individual carton uniquely using application identifier (00)



(Figure -3)

In the above example:-

(00)	Is the Application Identifier to indicate that the data following it is the numeric serial number of the Shipper/Carton/Tertiary level packaging.
189011070000000018	Is the 18 digit numeric serial no. of the Shipper/Carton/Tertiary level packaging.

Note:

- GTIN of tertiary level packaging should be different from GTIN of primary and secondary package.
- The above barcoding requirements shall be **in addition** to existing statutory labeling & marking requirements.
- The parentheses (brackets) are not encoded in the bar code and they are represented in human readable form only for highlighting the application identifier number with in the brackets.
- Fixed length data fields will always precede variable length fields.
- It is mandatory to print data encoded in barcodes as human readable information.
- In case the importing country has mandated a specific requirement, the exporter can adhere to the same and it would not be necessary to comply with the above requirement.
- For detailed specs refer to GS1 General Specifications available at : http://www.gs1india.org.in/gs1barcodes/pc_index.htm
- For any assistance, you can contact Shri. Gopal Valecha at 011- 26168720/721/725, Mobile: 99 103 50 103, email – gopal@gs1india.org